

**PILOT STUDY OF CEA RNA-LOADED, FLT3 LIGAND-MOBILIZED
PERIPHERAL BLOOD ANTIGEN PRESENTING CELLS FOR PATIENTS WITH
METASTATIC MALIGNANCIES EXPRESSING CEA**

NON-TECHNICAL ABSTRACT

No systemic therapy improves survival for refractory metastatic cancers such as colon, lung, and breast cancer. Interest in immunotherapy for these malignancies has been stimulated by the finding that specialized antigen presenting cells, dendritic cells (DC), can induce anti-tumor immune responses. We have performed clinical studies with DC loaded with the RNA encoding the tumor antigen CEA (found on many cancers including colon, bresat, and some lung cancers) and determined that they are safe when injected under the skin or into a vein. Furthermore, immune responses have been detected in some patients. The DC used in that study required considerable handling and seven days of culturing in flasks. We have found that it is possible to increase the number of DC in the blood by administering FLT3-ligand, a bone marrow cell stimulant. Therefore, it should be possible to increase the number of dendritic cells in the blood with FLT3-ligand, remove some of the cells and load them with CEA RNA, and then reinject the cells as a vaccine.

The overall objective of the phase I portion of the study is to evaluate the safety and tolerability of injections of CEA RNA-pulsed FLT3-ligand stimulated blood cells derived from the patient.